Commentary Regarding a Survey of Egg Production Firms Relative to *Salmonella* Enteritidis at the Production Site

Prepared by Donald Bell, Poultry Specialist (emeritus), University of California, December 6, 2004

The following comments relate to a survey of United Egg Producers (UEP) egg producer members and American Egg Board (AEB) members conducted in November 2004.

United Egg Producers (UEP) is a cooperative of U.S. egg producers based in Atlanta, Georgia. The association consists of 215 members who collectively own approximately 255 million laying hens – representing some 90% of the nation's table egg industry.

In October/November of 2004, a series of public meetings was held in different parts of the country to present a list of proposed *Salmonella* enteritidis (SE) rules to the egg industry. At that time, requests from the U.S. Food and Drug Administration (FDA) were also made for additional information regarding the proposals.

To gather information directly from producers relative to the FDA's request, a survey questionnaire was developed and mailed to the entire membership of UEP along with additional egg producers with questions concerning their present operations and possible effects of the proposed rule on their management and economic returns. Emphasis focused on the FDA's request for industry in-put regarding the proposed rule for the Prevention of *Salmonella* Enteritidis in Shell Eggs During Production. The purpose was to collect factual information about the egg industry that could be provided to the FDA.

The survey consisted of 37 questions and was done on a confidential basis without access to the names of the companies being surveyed. Questions were developed by Mr. Randy Green and Mr Howard Magwire with UEP, Dr. Hilary Shallo Thesmar with the Egg Nutrition Center (ENC) and Mr. Donald Bell with the University of California at Riverside. Mr. Bell compiled and analyzed the data.

Questions focused on the following subjects:

1. **Description of production facilities – packing plants, layer housing**
2. **Number of laying hens – in-line and off-line production**
3. **Environmental testing procedures and costs**
4. **History of Salmonella problems**
5. **Diversion of positive eggs – where and at what cost**
6. **Vaccination programs – vaccines and costs**
7. **Expenditures for rodent and pest control**
8. **House cleaning procedures and costs**
9. **Refrigeration of eggs – present systems and upgrade costs**
10. **Existing biosecurity programs – features and costs**
11. **Comments from producers**
12. **Trace back experiences**

Description of Production Facilities

The data was expressed in terms of the number of respondents and the percentage of total respondents. Zeros and "non-responses" were excluded from the calculations. In addition, a separate table groups respondents into 5 categories of replies for each question. Category 1 represents the highest 20% of response, categories 2,3, and 4 represent mid-range (median) responses, and category 5 represents the lowest numerical responses for approximately 20% of those responding concerning a particular question.

The accompanying tables describe the farms in terms of in-line vs off-line production, the number of packing stations operated by the company, and the number and size of laying houses.

Of the 44 completed surveys, 25% of the companies reported only in-line production facilities. (In-line refers to egg collection belts between production houses and the packing plant). Another 27% of the respondents reported only off-line production and the remainder reported a combination of both systems.

Thirty-four companies (85% of the total) reported that they operated 105 egg cartoning plants for an average of 2.9 plants per company. This represents plants operated exclusively as in-line operations, off-line, and combinations of the two procedures.

The respondents reported that 1,708 poultry houses supplied all of their needs. This represented almost 40 houses per company. Forty-four companies reported production on 387 farm sites which represents 8.8 farms per company and 6.9 houses per farm

[Note: This appears to be in general agreement with the 7.4 houses per farms of 100,000 or more hens reported in Table 6 of the FDA's Proposed Rules publication (Federal Register Sept 22, 2004)]

Number of Laying Hens

USDA NASS reports approximately 285 million table eggs layers during the Fall months of 2004. This survey represents 134.7 million laying hens or 47% of the Nation's flock. The 48 respondents of this survey reported 105.9 million hens in in-line operations and 28.1 million in off-line systems. This represents an average of 2.8 million laying hens per company, 8.8 farms per company 350,000 hens per farm, and 70,060 hens per house.

Table 1 describes the companies participating in the survey in terms of size.

Table 1. Distribution of company size

Category	Size	Number of Companies	%	Number of Hens	%
A	<250,000	5	10.4	603,000	0.5
B	250 to 500 thousands	7	14.6	2,470,000	1.8
C	500,000 to one million	7	14.6	5,540,000	4.1
D	one million to five million	23	47.9	53,236,000	39.5
E	>5 million	6	12.5	71,839,000	54.1
Total		48		134,688,000	

Environmental Testing Procedures and Costs

Of the 48 companies reporting, 39 (81.3%) conduct routine tests of the environment for SE. These tests are done to comply with the demands of the retailers (31.1%), the requirements of state quality assurance programs (37.8%) and for individual company quality control programs (31.1%). The most frequent areas for sampling are manure pits (44.9%), egg belts (26.1%), manure belts (13.0%) and "other" sites (14.5%). Testing averages $76.54 per sample (compared to the FDA estimate of about $45). The median estimate in the current survey is $51.33. Samples are commonly tested at state (56.1%) and private labs (29.3%).

Sampling costs (for one sample) vary from $147.60 (category 1) to $14.48 (category 5). This apparent wide variation may be due to the number of samples collected and the number of samples pooled for laboratory testing. No consistent standards appear to be used.

History of Salmonella Problems

Of the 48 companies who test the environment, 68.8% of the companies have never had a positive test; 25.0% have had positive environmental test experience. Three companies report they have had positive environmental and egg tests in the same house.

Diversion of Positive Eggs – Where and at What Cost

Of the 15 companies that report they test eggs if they find an environmental positive, only 3 of the egg samples were found to also be positive. A significant portion of participants in this survey (41.4%) believe that most egg breakers will not accept eggs that are known to be SE positive. Another 54.3% believe breakers will accept them, but at a discount. Overall, the average additional discount is believed to be about 10 cents/dozen. In 59.5% of the cases, a breaker is within 100 miles of the production sites. Another 28.6% are within 100 to 250 miles of a breaker and 9.5% are more than 250 miles from the nearest breaking plant.

Vaccination programs – Vaccines and Costs

Salmonella enteritidis vaccination is practiced by 54% of the 48 companies surveyed. Companies with 100+ million (74%) layers are currently vaccinating their flocks. Note: this does not mean that all the hens have been vaccinated. They use live vaccines (46.2%), killed vaccines (38.5%), and combination programs (15.4%). The average cost of the vaccination is reported to be 7.2 cents per bird for 2.4 vaccinations. Vaccination costs ranged from 15.6 cents per bird (category 1) to 1.7 cents (category 5).

Expenditures for Rodent and Pest Control

Forty-two companies reported costs for rodent and pest control attributable to SE. Obviously, these are both on-going programs irrespective of their relationship to biosecurity related to SE.

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The average company in this survey has approximately 2.8 million layers. The reported cost for rodent and pest control was reported to be $170,127 or $27.82 per 1000 hens. Total costs for this category for the companies in the survey were estimated to be in excess of $7 million. Costs per 1000 hens ranged from $83.34 to $3.53 for categories #1 and #5 respectively.

House cleaning Procedures and Costs

Cleaning houses between flocks ranges from almost $290 per 1000 hens to as little as $8. Average cleaning costs are reported to average $4,662 per house or $90.35 per 1000 hens. Obviously, the quality of cleaning varies considerably between the two extremes. The majority (63.6%) of farmers report that they dry clean and disinfect while 25% report that they routinely wet clean. Following a positive environmental test for SE, 65% report that they would wet clean while only 20% would dry clean. Many producers say that wet cleaning is not feasible in colder climate areas during the winter months.

Refrigeration of Eggs – Present Systems and Upgrade Costs

Some eggs are held unrefrigerated for 36 or more hours in the facilities of 8 (16.7%) of the 48 companies surveyed. Of the total farms controlled by the companies in this survey, 27.7% of the cooling equipment is incapable of cooling a storage room to 45 degrees F. Correction would be accomplished by purchasing new equipment by 61.5% of the companies or by upgrading existing equipment (38.5%) for an average cost of $70,000 per company.

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Existing Biosecurity Programs – Features and Costs

Current biosecurity programs include the following practices in order of frequency:

Restrict visitors – 93.8%
Sanitizing stations at house entrances – 68.8%
Equipment cleaned between houses – 54.2%
Limit employee movement between houses – 50.0%
Protective clothing for employees – 29.2%
Employees change clothing between houses – 14.6%

Currently, 29.2% of the companies surveyed include 4 or more of the above programs.

The cost of biosecurity programs vary from $107.55 per 1000 hens to $2.57 for categories #1 and #5 respectively. Average costs are calculated to be $95,153 per company or $38.79 per 1000 hens.

Comments From Producers

UEP has asked their members to submit written comments directly to the FDA relative to the proposed rules. The following comments were sent in with the survey forms:

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- **We need to use the 55 degree temperature to hold eggs at the farm.**
- **Use good farm records as proof of an effective SE control program and not mandate vaccination when not needed.**
- **Our major concern is diverting SE positive eggs to the breakers. There are fewer offline breakers every year. Will there be enough around in future years? The discounts and marketing loss will be huge.**
- **No longer do environmental testing - egg testing is much more accurate.**
- **Cooling eggs to 45 degrees before washing will sharply increase numbers of thermal checks.**
- **Contract farms pay for C & D and rodent and fly control.**
- **Each employee has a clean set of coveralls every day.**
- **Eggs on contract farms held at 60 degrees**

Trace Back Experiences

Of the 48 companies, 9 (20.5%) have been involved in SE tracebacks. All were successfully cleaned and disinfected followed by negative tests.

UEP Salmonella Enteritidis Survey - November, 2004

Distribution of Answers

(Zeros and no responses were excluded from the averages)

Question #	Question	Companies	Highest one-fifth	2	3	4	Lowest one-fifth	Total	Average
2	How many packing stations does your company have?	37	9.1	3.1	1.7	1.0	1.0	115	3.1
3	How many henhouses supply all your operations (in-line + off-line)?	47	121	47	23	10	5	1897	40.1
4	If you are off-line or partly off-line, how many total farms supply your packing operations?	35	22.9	7.4	4.6	2.9	1.1	272	7.8
4a	How many total farms (est)?	44	25.8	8.2	5.1	3	1	387	8.8
4b	Estimated houses per farm?	43	19.5	6.6	3.6	2.5	1.5	n/a	6.9
5	Number of layers under your control - in-line	34	9,903,429	2,707,143	14,125,000	841,667	228,167	105,943,000	3,115,971
5a	Number of layers under your control - off-line	39	1,861,375	802,500	440,000	273,571	126,286	28,070,000	719,744
5b	Number of layers under your control-total	48	8,829,500	2,572,000	1,256,667	642,222	203,667	134,688,000	2,806,000
5c	Calculated hens per house	47	116,884	91,792	71,793	47,731	22,216	n/a	70,060
9	Total environmental testing costs for one sample	31	147.60	97.50	51.33	28.33	14.48	n/a	76.54
16	What is the normal discount betweeen shell and breaker egg prices?	25	43	28	17	9	4	n/a	20
17	What added discount if known to be SE eggs (estimated)?	18	21	11	7	6	1	n/a	10
19	Total cost of SE vaccination (including vaccine + labor in cents/bird.	24	15.6	8.8	6.1	2.6	1.7	n/a	7
21	Annual expenses for rodent and fly control attributable to your SE program	38	806,250	61,875	15,875	7,900	2,576	7,145,335	170,127
21a	Calculated cost per 1000 hens.	38	83.34	32.09	19.59	9.10	3.53	n/a	27.82
24	Present cost to C & D one house	37	12,938	4,938	2,386	1,307	519	n/a	4,662
24a	Calculated C & D cost per 1000 hens	35	289.03	85.79	39.24	19.30	7.97	n/a	88.27
28	If new refrigeration is needed to reach 45 degrees - estimated cost of upgrade and/or new equipment	20	164,250	106,250	48,750	21,250	8,000	1,394,000	69,700
31	Present total cost of biosecurity program	37	351,250	70,313	24,143	8,714	1,900	3,615,800	95,153
31a	Calculated cost per 1000 hens.	36	107.55	41.83	21.65	9.68	2.57		38.79

UEP Salmonella Enteritidis Survey - November, 2004

Summary of Results by Questions

Question # — **Question** — **Responses**

1 Is your company (in-line, off-line) ?

n	In-line No.	% of total	Off-line No.	% of total	Both No.	Both % in-line
44	11	25.0	12	27.3	21	47.7

2 How many packing stations do you have?

n	No. of companies with plants	% of companies with plants	Total plants	Average/ company
40	34	85.0	105	2.9

3 How many total henhouses supply all your operations (in-line + off-line)?

n	Total houses	Average/ company
44	1708	38.8

4 If you are off-line or partly off-line, how many total farms supply your packing operation?

n	Total farms	Farms/ company
35	272	7.8

4A How many total farms? (calculated)

n	Total farms	Farms/ company	Houses/farm
44	387	8.8	6.9

5 How many total layers under your control?

n	Total in-line	Total off-line	Total	Avg in-line	Avg off-line	Avg total	Calculated hens/house
48	105,943,000	28,070,000	134,688,000	3,115,971	719,744	2,806,000	70,060

6 Do you presently carry our environmental testing?

n	Yes	%	No	%
48	39	81.3	9	18.7

6A Do you presently test eggs routinely?

n	Yes	%	No	%
48	1	2.1	47	97.9

7 If yes, do you test because of ?

(more than one answer is possible)

Customer reqt. (no.)	Comply/state program (no.)	Other (no.)	Customer reqt. (%)	Comply/state program (%)	Other (%)
14	17	14	31.1	37.8	31.1

8 If yes, which areas do you sample (e.g., manure pit, egg belts) ?

(more than one answer is possible)

Manure pits (no.)	Manure belts (no.)	Egg Belts (no,)	Other (no.)	Manure pits (%)	Manure belts (%)	Egg Belts (%)	Other (%)
31	9	18	10	44.9	13	26.1	14.5

9 what do you estimate is your total cost (including labor, materials, and laboratory costs) for one environmental test in one house? (one sample)

n	$ per sample
31	76,54

10 Do you send your samples to?

(more than one answer is possible)

State Lab (no,)	Private lab (no.)	In-house lab (no,)	Combination (no.)	State Lab (%)	Private lab (%)	In-house lab (%)	Combination (%)
25	12	4	2	56.1	29.3	9.8	4.9

11 Do you presently test eggs if an environmental test is positive?

n	Yes	%	No	%
36	15	41.7	21	58.3

12 If so, what size egg sample would you use?

Yes	Number
13	803

13 What do you estimate is your total cost for a one-time egg testing in one house?

Number	$/house
17	400

14 To your knowledge, have you hever had?

Positive environ. test (no.)	Positive egg test (no.)	Both in the same house (no.)	No positives (no,)	Positive environ. test (%)	Positive egg test (%)	Both in the same house (%)	No positives (%)
12	0	3	33	25	0	6.3	68.8

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15 Based on your experience and judgement, do you believe that if eggs must be diverted from an operation because of a positive egg test ?

Most breakers will refuse to take them (no.)	Most breakers will accept them, but at a discount (no.)	Break their own eggs (no.)	Most breakers will refuse to take them (%)	Most breakers will accept them, but at a discount (%)	Break their own eggs (%)
19	25	2	41.3	54.3	4.3

16 What normal discount would you expect to receive for eggs sold to a breaker, compared to eggs sold for the table market?

n	Cents per dozen
25	20.4

16A Is there a breaker near-by?

Within 100 miles (no.)	Within 250 miles (no.)	On site (no.)	Neither (no.)	Within 100 miles (%)	Within 250 miles (%)	On site (%)	Neither (%)
25	12	1	4	59.5	28 6	2 4	9.5

17 What additional discount, if any, would you expect to receive for eggs sold to a breaker if the breaker know the eggs were being diverted because of SE?

n	Cents per dozen
18	9.7

18 Do you vaccinate for SE ?

n	Yes (no.)	No (no.)	Yes (%)	No (%)
48	26	22	54.2	45 8

18A If yes, do you use?

Live vaccine (no.)	Killed vaccine (no.)	Combine (no.)	Live vaccine (%)	Killed vaccine (%)	Combine (%)
12	10	4	46.2	38.5	15.4

19 If yes, wht is the total cost per bird for vaccination? How many vaccinations per bird?

n	Cost per bird (cents	No. vaccinations per bird
24	7.2	2.4

20 Do you obtain chicks and pullets only from NPIP SE Monitored flocks?

n	Yes	%	No
47	47	100	0

21 Approximately what is your total annual expenditure for rodent and fly control attributable to your SE program?

n	$ per company	Calculated $/1000 hens	Total $ in survey
42	170,127	27.82	7,145,335

22 At depopulation of a house that is negative for SE, do you presently ?

(more than one answer is possible)

Dry clean & disinfect (no.)	Wet clean & disinfect (no.)	Both (no.)	Dry clean only (no.)	Dry clean & disinfect (%)	Wet clean & disinfect (%)	Both (%)	Dry clean only (%)
28	11	4	1	63.6	25 0	9 1	2.3

23 If you have a house with a positive environmental test, do you presently ?

Dry clean & disinfect (no.)	Wet clean & disinfect (no.)	Both (no.)	Dry clean only (no.)	Dry clean & disinfect (%)	Wet clean & disinfect (%)	Both (%)	Dry clean only (%)
5	16	4	0	20 0	65.0	16.0	0

24 Approximately what would you estimate is your cost to clean and disinfect one house?

n	$ per house	$ per 1000 hens
37	4,662	90.35

25 In you operation, are eggs ever held more than 36 hours before being refrigerated (for off-line operations, count the time from laying on a contract farm to refrigeration at the packing facility)?

n	Yes	%	No	%
48	8	16 7	40	83 3

26 Does your operation, including any contract farms, presently have coolers that can refrigerate eggs at an ambient (not internal) temperature of 45 degrees F?

n	Yes	%	No	%	At packing house but not at farm (no.)	At packing house but not at farm (%)

47	27	57.5	13	27 7	7	14 9

27 If so, what would you have to do in order to achieve refrigeration at 45 degrees F?

Purchase new equip. (no.)	Upgrade exist. Equip. (no.)	Purchase new equip. (%)	Upgrade exist. Equip. (%)
16	8	61.5	38.5

28 If so, what would you estimate to be your total cost to achieve refrigeration at 45 degrees F through new equipment purchase or upgrading?

n	$ per company	$ per survey
20	69,700	1,394,000

29 If so, do you presently have coolers that can refrigerate at an ambient temperature of 55 degrees F?

n	Yes	%	No	%
38	37	98 9	1	2.8

30 Do you presently have a biosecurity program that? (Yes)

(more than one answer is possible)

n	Restricts visitors	Equip clean between houses	Protective clothing for employees	Sanitizing stations	Limits employee movement between houses	Employees change clothing between houses	Use 4 or more procedures
47	45	26	14	33	24	7	14

30A Do you presently have a biosecurity program that? (%)

n	Restricts visitors (%)	Equip clean between houses (%)	Protective clothing for employees (%)	Sanitizing stations (%)	Limits employee movement between houses (%)	Employees change clothing between houses (%)	Use 4 or more procedures (%)
47	93 8	54.2	29.2	68.8	50.0	14.6	29.2

31 What do you estimate is your present total annual spending on biosecurity (personnel, equipment, supplies, testing, etc)?

n	$ per company	$ per 1000 hens	$ per survey
38	95,153	39.42	3,615,800

32 Please make and additional comments· (see attachment)

Not applicable

33 Have any of your facilities ever been involved in an FDA traceback investigation?

n	Yes	%	No	%
44	9	20.5	35	79.6

34 If so, were your faciilties ?

n	Positive (no.)	%	Negative (no.)	%
8	5	62.5	3	37.5

35 What were your approximate costs to work with FDA during the traceback ?

n	$ per company	$ per survey
5	4,440,224.00	22,201,120.00

36 If your facilities were positive, what was your approximate post-traceback cost to eliminate SE at your facility?

n	$ per company	$ per survey
3	1,835,000	5,505,000

37 Were you able to test negative after your cleaning and disinfection procedures ?

n	Yes	%	No
5	5	100	0

USDA

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Dear Mr. Gregory,

Per your request, I am providing a synopsis on the issue of how molting might impact food safety in view of my recently published research on the subpopulation biology of *Salmonella enteritidis*. This information about the biology of *Salmonella enteritidis* (*S. enteritidis*) provides a scientific basis for understanding why the European and the USA experience with egg contamination by *Salmonella enteritidis* has differed. The fact that the USA uses molting routinely, whereas the European Union has banned it, is perhaps one of the largest epidemiological studies every conducted. I am not sure that I could have devised a better experiment to test the issue of whether or not molting impacts the safety of the food supply. The epidemiological outcome strongly suggests that molting does not impact food safety associated with the problem of egg contamination, because Europe still has a much worse problem than does the United States.

I have divided the synopsis into sections for ease of reading, and I believe that it is important to have a literature review on the subject, especially because there must be firm scientific footing when considering a major change in management practice in any intensive farming situation.

Sincerely yours,

Jean Guard Bouldin
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TITLE: The impact of molting on human illness associated with egg-contaminating *Salmonella enteritidis*: A contrast of the European and USA experiences

AUTHOR: Jean Guard Bouldin, D.V.M., Ph.D., USDA-ARS-SEPRL

INTRODUCTION

Salmonella enterica serovar Enteritidis (*Salmonella enteritidis*, *S. enteritidis* or SE) contaminates the internal contents of eggs collected from otherwise healthy appearing hens, which is a biological phenomenon that has contributed to its emergence as the leading cause of salmonellosis worldwide and as the second leading cause in the United States. Molting of the egg laying hen is a management practice that intentionally withholds feed to induce a period of reproductive rest so that a second cycle of egg production can occur. Molting is known to increase fecal shedding of *S. enteritidis*. This fact has been used as evidence that molting is a hazard to food safety and that it should be banned. However, Europe banned molting and it has a worse problem with egg contamination than does the United States. Recent research on the subpopulation biology of *S. enteritidis* provides a better scientific understanding of how differences in molting practices might impact the incidence of egg contamination. Thus, in the absence of scientific evidence that molting is a hazard to food safety, there is no scientific basis for banning this management practice in the United States in regards to protection of the food supply. Abandoning molting could have unintended consequences, because it is not possible to predict how such a drastic change would alter the balance of *S. enteritidis* subpopulations that vary in their ability to contaminate eggs.

LITERATURE REVIEW

There is overwhelming scientific evidence that molting increases fecal shedding and transmission of *S. enteritidis* in the hen-house. However, only 1 of the 4 papers cited by the 1998 FSIS Risk Assessment refers to culturing eggs, and in that paper, one of two trials was negative for egg contamination (21). The *Salmonella enteritidis* pilot project cited by the committee, which was not a peer reviewed journal article, reported a two-fold increase in egg contamination in molted hens as compared to non-molted hens (32). Research on molting that came out after publication of the Risk Assessment continues to show a strong correlation with fecal shedding and transmission of *S. enteritidis* between hens, but it does not shed any further light on a positive correlation with egg contamination (5, 14, 16-19, 24, 25, 33). The 1998 FSIS Final Report (pg 40) cites these studies as providing evidence that molting is a major contributor to egg contamination (13, 15, 20, 21, 32). However, when the committee reviewed all of the data, the conclusion was that "…the variables associated with molting are not correlated with the output of the production module (page 66)."

The next sentence made by the panel suggests that there was bias towards overweighting the effect of molting on egg contamination as reported by the field study. The committee reported that "Such results are surprising given the much higher frequencies at which molted flocks produce SE-positive eggs". The phrase "much higher frequency" should have been debated, because a 2 fold difference is considered within baseline variation in experimental animal studies. Essentially this means that the panel erred on the side of caution in factoring in some slight risk associated with molting.

CURRENT RESEARCH ON THE BIOLOGY OF *SALMONELLA ENTERITIDIS*

The 1998 Risk Assessment identified that the emergence of the high prevalence flock is what poses the greatest risk to the consumer (pg 66-67). Overtime, my collaborators and I have provided a preponderance of evidence that *S. enteritidis* generates distinct subpopulations that have variable potential to contaminate eggs.(6, 7, 9-12, 22, 23, 26-31). One subpopulation appears to be only a weak pathogen and it dominates in the intestines of hens. It can result in experimental egg contamination if hens are artificially dosed with high numbers, which is unlikely to occur on the farm. A second subpopulation makes a biofilm, which is a tough organic matrix that protects cells and it is better than the others at oral invasion and invading organs. However, it does not contaminate eggs . A third subpopulation makes a capsule that correlates with a specific interaction with the avian reproductive tract and with high cell density growth. This third subpopulation has been identified as resulting in high frequency egg contamination in our experimental challenge model. High incidence egg contamination following low dose contact exposure of hens in experimental settings has only happened when the second and third subpopulations are combined. The house mouse *Mus musculus* has been shown to be an important contributor to egg contamination, in part because it is a natural reservoir for all three of these subpopulations. Further research strongly suggests that different organs and sites within the intestinal tract of the hen are colonized by different subpopulations (8). This means that the hen herself is applying stringent selection pressure on the overall balance of subpopulations that it sheds into the environment. The impact of this finding is that a molted hen may shed a very different balance of subpopulations into its environment as compared to a non-molted hen.

LESSONS FROM THE EUROPEAN EXPERIENCE

There is now a decade of results from Europe that contrasts sharply with the experience of producers in the United States. Surveillance of the incidence of *Salmonella* serotypes in humans for the second quarter of 1999 in Europe showed that *S. enteritidis* comprised 66.3% of the isolates, whereas second place *S. typhimurium* was associated with 13.4% of cases (1). In the third quarter of 2001, these figures were 75.4 and 10.6% for the same two serotypes respectively (2). In contrast, the latest available figures on the prevalence of *Salmonella* serotypes in humans in the United States reported that 21.9% of isolates from human cases were *S. typhimurium* and 15.8% were *S. enteritidis* (4). Since the emergence of pandemic salmonellosis has had a high correlation with the emergence of egg contamination by *S. enteritidis* (3), these figures indicate that the European and United States experiences are drastically different. Thus, the preponderance of evidence indicates that molting, which is practiced in the United States, does not correlate with an increase in egg contamination. It can even be suggested that molting may correlate with a decrease in human illness from *S. enteritidis*. However, in the absence of targeted research that tests such a hypothesis, it is more appropriate to summarize that there is no association of molting with increased egg contamination.

EVIDENCE DOES NOT SUPPORT A BAN ON MOLTING BY THE USA

The European ban on molting occurred at the same time that the USA insisted on keeping it as a legitimate management practice. It is possible that this inadvertent contrast between continent-specific husbandry practices set up one of the largest population-based experiments ever conducted. Research now shows that *S. enteritidis* has a unique biology that contributes to high incidence egg contamination. Molting encourages intestinal shedding and the current research on subpopulation biology strongly suggests that the intestinal form of *S. enteritidis* does not make it to the egg at high frequency. The cecum of the hen was identified as an anatomical site where a subpopulation that is specifically adapted to the avian reproductive tract emerges. *S. enteritidis* thus appears to be a pathogenic bacterium that has developed niche specialization and that goes ever deeper within its host to find a favorable site to live. It is possible that molting is providing a type of vaccination, or a type of competition, that is suppressing wide spread emergence of the most dangerous subpopulations within the United States. Research in the future should help reveal more information about factors that most directly contribute to high incidence egg contamination. However, the contrast between the European and the United States experience provides a scientific foundation for deciding that the United States should not abandon molting as a management practice. To do so at this time, in the absence of evidence from Europe that they have reduced levels of egg contamination below that of the United States, is to jump to a premature conclusion that could have unintended consequences for the safety of the food supply.

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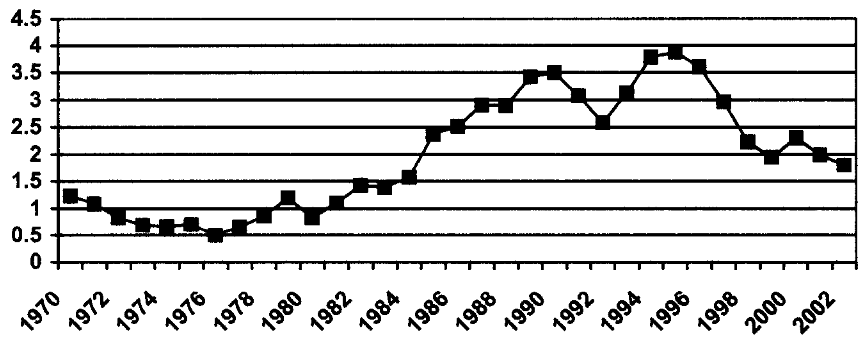
Salmonella Enteritidis Update
2004

Salmonella Enteritidis (SE) continues to be an organism of concern for the egg industry since SE has the ability to internally contaminate eggs. The Centers for Disease Control and Prevention (CDC) in Atlanta track *Salmonella* illnesses in the US and issue annual reports on Salmonella and other foodborne illnesses.

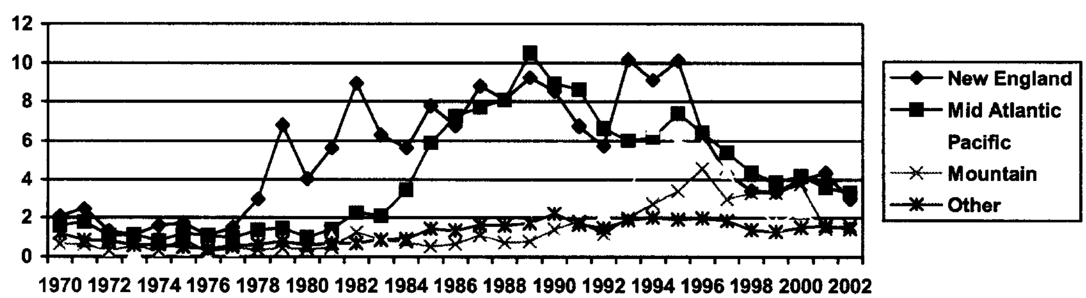
The first two figures below are from the *Salmonella* Surveillance system (http://www.cdc.gov/ncidod/dbmd/phlisdata/salmonella.htm), which tracks all Salmonella illnesses in the US and each year publishes an annual summary. In the most recent summary, Salmonella Annual Summary 2002, *Salmonella* Typhimurium was the most common serotype causing 21.9% of all human salmonellosis illnesses. *Salmonella* Enteritidis was ranked number two causing 15.8% of all human salmonellosis illnesses. Data for SE is shown in the figures below. SE cases peaked in the mid 1990's and dropped in the late 1990's. The decrease has leveled off the last few years and the reason is unknown.

Figure 1. *Salmonella* Enteritidis Cases
Rate per 100,000 by year 1970-2002



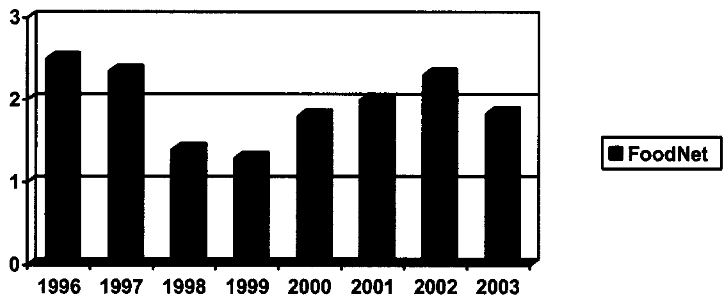
From the mid 1980's through the mid 1990's, SE was primarily a problem in the northeastern part of the US. In the mid 1990's the incidence of SE leveled off in the northeast and increased in other areas of the US. SE was thought to be a regional problem for many years, however it is now seen as a nationwide problem with similar illness rates in all areas.

Figure 2. *Salmonella* Enteritidis by Region 1970-2002



The FoodNet Program is the CDC's Foodborne Diseases active surveillance Network which tracks illnesses due to nine common foodborne pathogens (http://www.cdc.gov/foodnet). FoodNet gives us a snapshot of what pathogens are causing illnesses, however, foods are not associated with the pathogens unless cases control studies are done on more detailed data. The incidence of SE illnesses per 100,000 persons is in Figure 3 below. From 1996 to 1999, FoodNet data indicated a significant drop in the incidence of SE. From 1999 to 2002, that reduction had almost reversed to the incidence seen in 1997. The Food and Drug Administration has expressed concern that the FoodNet data no longer shows a significant reduction in SE illnesses. The 2003 Preliminary FoodNet report stated that the incidence of SE varied from year to year and has not changed significantly. The reduction from 2002 to 2003 is primarily due to an increase in population in the FoodNet sites, while the number of illnesses remained similar to past years.

Figure 3. FoodNet: *Salmonella* Enteritidis illnesses per 100,000 persons 1996-2003.



The *Salmonella* Enteritidis Outbreak Surveillance System of the CDC tracks all SE outbreaks and attempts to associate an outbreak with a food source (http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salment_a.htm). Based on the outbreak investigation, a traceback investigation may be completed to link the outbreak to a contaminated farm. Not all SE outbreaks are due to eggs; however, if eggs are included in mixed food items, the outbreak is recorded as egg associated. Historically, between 55% to 80% of SE outbreaks have been linked to shell eggs. However, in 2002, approximately 10% of all illnesses due to SE outbreaks were egg associated outbreaks. In recent years, SE outbreaks have been caused by non-egg foods such as juices, salsa, meat, sprouts, fruit and salads. The majority of the outbreaks are caused by a number of things going wrong including lack of refrigeration, improper handling and inadequate cooking.

The next four charts (Figures 4-7) show data from SE outbreaks in recent years. The number of outbreaks peaked in 1990 and has remained at approximately 45-50 outbreaks per year for the previous 5 years in which the CDC has published data. The number of SE outbreaks dropped to 29 in 2002.

Figure 4. CDC SE Outbreak Surveillance System
SE Outbreaks: Number of Outbreaks per year 1985-2001

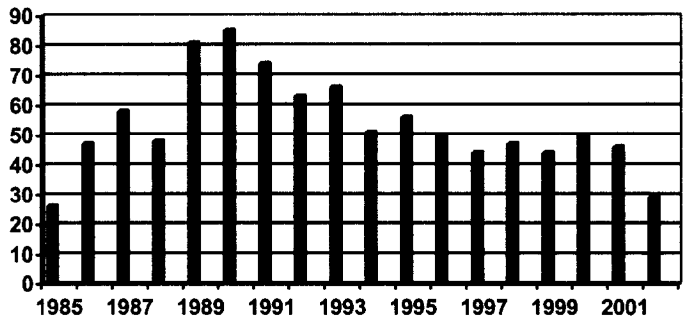
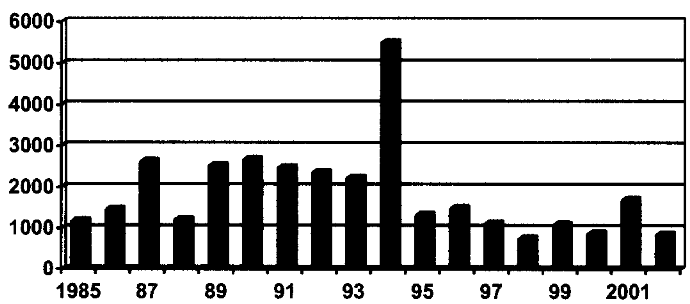


Figure 5. Total reported SE cases in outbreaks 1985-2001



The total number of SE cases due to outbreaks had been fairly stable at approximately 700 to 1000 cases each year. However, a large increase in 2001 was a concern for public health professionals. There were three very large outbreaks in 2001 in which eggs were associated. The largest outbreak caused 688 illnesses and the cause was suspected to be tuna salad with egg. The source of the SE was either the eggs, which were supposedly hard cooked, or food handler contamination. This outbreak occurred at a prison in South Carolina. The second largest outbreak was in Virginia and was caused by a raw egg spread at a deli which sickened 231 people. The third largest outbreak was 113 illnesses in North Carolina that were statistically linked to egg consumption. No food source was identified. The total of these three outbreaks was 1032 illnesses, which accounted for 61.4% of all illnesses in all 46 SE outbreaks in 2001. Of note, only one outbreak of 46 was traced back to SE isolated from an egg farm (the outbreak that caused 688 illnesses). Other traceback investigations were completed, however SE was not identified on the farms. The CDC published a report on SE illnesses due to shell eggs in Morbidity and Mortality Weekly Report (MMWR) on Jan 3, 2003 (http://www.cdc.gov/mmwr/PDF/wk/mm5151.pdf).

The 2002 outbreak report identified 29 outbreaks with a total of 840 illnesses. Four traceback investigations were completed with one identifying a single farm as the source of SE contamination.

Figure 6. 1998-2001 CDC Outbreak Data for *Salmonella* Enteritidis (as Percent)

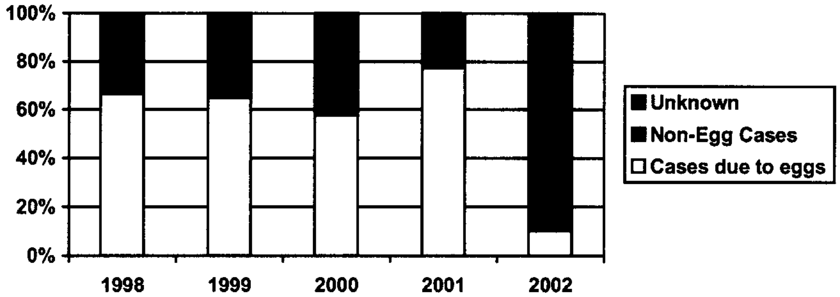
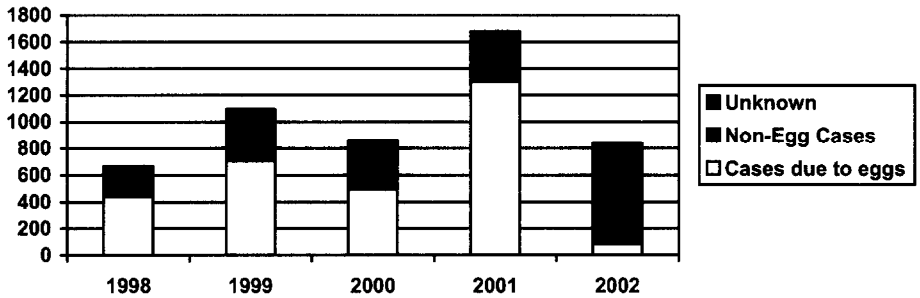


Figure 7. 1998-2001 CDC Outbreak Data for *Salmonella* Enteritidis (total number of cases)



The egg industry continues to take actions to prevent SE infections in laying hens and in eggs. Most of the industry has adopted voluntary quality assurance programs and vaccination has become more common. The FDA SE Prevention Proposed Rule was published in September of 2004. USDA's proposed rule is expected anytime. The goal of the proposed egg safety regulations is to reduce SE infection in eggs by 50% and ultimately by 100%.

An important part of preventing SE illness from eggs depends on educating consumers and food preparers to properly refrigerate, handle, and cook raw shell eggs. The American Egg Board is a founding member of the Partnership for Food Safety Education and the FightBAC!® Campaign. The American Egg Board provides food safety information to consumers and to food service professionals through their programs. The Egg Nutrition Center supports those efforts with technical and scientific information in addition to providing materials for health care professionals.

For more information on egg safety, contact the American Egg Board (www.aeb.org) or the Egg Nutrition Center (www.enc-online.org).

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From available data as of October 7, 2004

Egg Processors Survey
Results

The egg processing industry initiated a survey to identify current receiving and processing practices related to food safety. About one-third of the processors responded to the survey. The survey form and the response of the various processors are included as attachments. A summary of the results is as follows:

1. What reduction in pathogen load do you typically achieve in your processing operation?

Of those responding, 50% indicated that they achieved a 5 log reduction. The remaining reported log reduction of 7 logs or greater depending on the egg product. All respondents indicated that they achieve a minimum of a 5 log reduction in bacterial load. Half of the companies indicated that they achieve a 7 log reduction or greater in bacterial load.

2. If your answer to question 1 was greater than 5 log, is this because of:

One company indicated that a greater log reduction was required by the customer while two processors reported that company policy required a 7 log reduction. Others reported that certain products and process efficiency dictated a 7 log reduction.

It would be pointed out that many processors and customers have established specifications for maximum bacterial loads in egg products.

3. **How do you verify the log reduction achieved in your process?**

In most cases (7), processors verified log reduction by established time-temperatures requirements for a specific product. Others (4) also verified by measurement of bacterial load. One processor also estimated a total reduction of bacterial load including warm up and cool down times. Another processor indicated that log reduction depended on the product and its intended use. They emphasized D values for pathogens and flow conditions. It is well-known that flow conditions in the holding tubes as well as come-up and cool down conditions are important factors in determining the kill of Salmonella. This aspect will be further discussed later in this letter.

4. **Does the log reduction achieved vary from product to product?**

5. **If so, please provide estimates by product.**

Three firms reported that log reduction varied from product to product while 7 indicated no difference in log reduction between products. Of those mentioning variation from product to product, one indicated that they had the biggest cushion above 7 logs for whole eggs and whole egg products with non-egg ingredients and the least with yolk. Others mentioned egg white which has great sensitivity to heat. It is well-known that egg white pH can be a major factor in achieving a good kill of Salmonella. Egg white can be easily denatured therefore requiring lower pasteurization temperatures to avoid loss of functional properties. Another processor indicated the highest log reduction from whole eggs. One processor using a 7 log reduction on some egg products indicated that they used the 5 log guideline for salted products due to the stringency of salt. Salted yolk does present a different problem due to its high viscosity. Because of this, the data reported in the International Egg Pasteurization Manual (2002) recommends increasing the holding time to 4.5 minutes at 63.3°C for salted yolk. Established science shows that there is less growth of organisms in these products due to decreased water activity.

6. Do you have information on the pathogen load in eggs entering your facility?

Four processors reported that they had information on the pathogen load in eggs entering their facility while six had no data on bacterial loads entering the plant.

7. If so, please specify.

Two plants tested raw egg products in the breaking room, raw product vats and tankers for APC, yeast and molds. Another plant indicated that they routinely plated incoming raw egg products. One firm completed a study in 1998 which showed that 34% of the incoming egg tankers were positive for Salmonella. The level, however, varied from 0.003 cfu/gram to 1/1 cfu/gram which was quite low.

8. Are the incoming eggs you receive for processing:

a. _1_ **From in-line production**

b. _6_ **From off-line production**

c. _2_ **A mixture of both types**

d. _3_ **From tankers**

As one can see, the preponderance of respondents receive egg from off-line production. Two reported a mixture of off-line and in-line production. Regardless of the source of production today it is readily known that eggs reach the plants rapidly under present day conditions. Generally, eggs are in the plant within 3 to 4 days after production or sooner. Thus, the quality of eggs reaching the plant is greatly improved over that achieved years ago. Also, bacterial loads should be much lower.

It should be emphasized that all eggs are washed and sanitized at the plant. Hutchison et al, 2004 (J. of Food Protection 67:4-11) reported that washing inoculated eggs resulted in a 5 log reduction in Salmonella. The risk assessment does not address washing of eggs but we know that good washing procedures greatly reduce bacterial loads on the shell prior to entering the breaking operation. It is difficult to envision the bacterial loads indicated in the risk assessment. Several studies have indicated that it takes from 20 to 22 days for Salmonella to penetrate a shell at temperatures of 6 to 16°C. (Bigland and Papas, 1953; Can. J. Comp. Med. Vet. Sci: 17:105-109; Dolman and Board, 1992 Epidemiol. Infect. 108:115-121).

9. Do you test for…

a. _0_ Salmonella prior to pasteurization

b. _6_ Standard plate count prior to pasteurization

c. _2_ Other

Those processors mentioning "other" indicated that they also tested for coliforms and E. coli. It is known that coliforms can be used as in indicator organism for Salmonella.

10. Do you adjust your pasteurization procedure based on incoming product?

No firms reported any adjustment of pasteurization procedures based on incoming load in the product.

11. **Do you test for…**

a. **_10_ Salmonella post-pasteurization**

b. **_10_ Standard plate count post-pasteurization**

c. **__8_ Other**

All plants reporting tested post-pasteurization for Salmonella and standard plate counts. Others included E.coli, yeast, mold, Listeria and Staphylococcus. Thus, plants routinely test for Salmonella to assure that the product is Salmonella negative prior to shipping.

12. **Do you use SE vaccines or buy eggs from companies who vaccinate flocks?**

Two companies reported that they received eggs from vaccinated flocks while three indicated they did not know. Five companies reported that they did not obtain eggs from vaccinated flocks.

The risk assessment did not mention vaccination. Egg processors, as well as shell egg producers, commonly use vaccines as a control measure to protect hens from Salmonella colonization.

13. **If you answered "yes" to question 12, do you or your supplier use…**

a. **___ Live vaccine**

b. **_1_ Killed vaccine**

c. **_1_ Combination of live and killed vaccine**

14. **If you answered "yes" to question 12, approximately what percentage of your eggs come from vaccinated flocks?**

Based on the two companies reporting that they used vaccines, one indicated that 30% of these eggs came from vaccinated flocks while the other processor reported that 85-90% of their eggs came from vaccinated flocks.

15. Are you aware of any instance of documented illness from consuming pasteurized egg products? From your facility or another egg processor.

All processors answered no to this question.

I note that the risk assessment estimated that 50,000 to 100,000 illnesses result from pasteurized egg products. After the egg inspection act was implemented, to my knowledge there has not been a Salmonella outbreak from egg products.

Additional Comments Relating to the Draft Risk Assessment

1. Pasteurization results – FSIS utilized the raw data from the University of Nebraska study by United Egg Assocation and the American Egg Board. They had a concern for the non-linear results. With that in mind, FSIS transformed the data. The final results were slightly different than those reported in the University of Nebraska Study and published in the (International Egg Pasteurization Manual (2002). This study utilized the capillary tube method which had the advantage of an instant come-up time. Schuman et al (J. of Food Protection 60:231-236) in 1997 observed that capillary tubes gave more accurate D values than those scientists using larger tubes. For example, Michalski et al, 1999 (J. of Food Protection 62:12-117) compared results using the capillary tube method to that obtained from a plate heat exchange. The capillary tube method indicated that all processes gave less than a 9 D kill as recommended by the USDA.

However, when using the plate heat exchanger they obtained a greater than 9 D process for Salmonella. This indicates that the plate heat exchangers used in plants likely give a better kill which is partially due to the longer come up and cool-down time. Capillary tubes on the other hand are heated and cooled instantaneously. Another consideration is the flow characteristics in tubes in plant heat exchanges. Egg products may exhibit either laminar or turbulent flow. If the product is viscous, laminar flow may be prevalent. If laminar flow is predominant, the holding time needs to be adjusted since the fastest moving particle will flow twice as fast. Current regulatory requirements for pasteurization times and temperatures assumed laminar flow as a precautionary measure. However, if the line of flow is broken, turbulent flow is indicated and there will be greater mixing. Since egg pasteurizers holding tubes have turns, the minimum holding times provide a safety margin. The risk assessment does not emphasize flow characteristics and its importance in pasteurization technology in plants.

The risk assessment did not discuss the hydrogen peroxide pasteurization methods used for egg white by some processors. These methods (Armour and Standard Brands) are discussed in detail in the International Pasteurization Manual. Studies accomplished at Oklahoma State University showed that the Standard Brands method provided a 9 log reduction at all pHs when using a temperature of 55.8°C in combination with hydrogen peroxide. These results were also recently published by Robertson and Muriana, 2004 (J. of Food Protection, 67:1177-1183).

2. The national baseline survey is mentioned but detailed results are not available.

3. Clustering of Salmonella was mentioned as a possibility in egg products. I am not aware of any studies where clustering would be a problem in unpasteurized egg products. Using the Weibull distribution to determine a factor of 3 would greatly exaggerate the actual levels of Salmonella.

4. Research needs discussed in the risk assessment should be of value. Studies to date indicate a much better kill of Salmonella when using in-plant pasteurizing equipment as compared to the benchtop capillary tube method. There are pilot plants available which would answer this question using inoculation studies. Any pasteurization studies should also emphasize the effect on functional properties in the final product. The market for egg products depends on optimum functional properties.

One final issue needing an answer is the pH break-point where we reach an optimum kill of Salmonella in egg white. It is felt that this break-point is around pH 8.9 or 9.0, but we do not have an absolute answer.

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Submitted on December 2, 2004 by

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University of Nebraska

Enc. Egg Processors Survey
Comments from Survey

Egg Processors Survey

ANONYMOUS SURVEY – PLEASE DO NOT INDICATE YOUR COMPANY

1. What reduction in pathogen load do you typically achieve in your processing operation? (Check one.)
   a. _5_ 5 log
   b. ___ 6 log
   c. _3_ 7 log
   d. _2_ Other (Please specify: __________)
2. If your answer to question 1 was greater than 5 log, is this because of –
   a. _1_ Customer requirements
   b. _2_Company policy
   c. _3_ Other (please specify)
3. How do you verify the log reduction achieved in your process?
   a. _7_ Conformity with established time-temperature parameters
   b. _4_ Measurement of bacterial load
   c. _1_ Estimate of overall reduction in bacterial load, including during warm-up and cool-down times before and after holding at required temperature for required time
   d. _1_ Other
4. Does the log reduction achieved vary from product to product?
   a. _3_ Yes
   b. _7_ No
5. If so, please provide estimates by product. ________________________________
6. Do you have information on the pathogen load in eggs entering your facility?
   a. _4_ Yes
   b. _6_ No
7. If yes, please specify. ________________________________
8. Are the incoming eggs you receive for processing (check only one) –
   a. _1_ From in-line production?
   b. _6_ From off-line production?
   c. _3_ A mixture of both types (approximate % of off-line
   d. _3_ From tankers
9. Do you test for
   a. ___ Salmonella prior to pasteurization?
   b. _6_ Standard plate count prior to pasteurization?
   c. _2_ Other (please specify ________________________________)
10. Do you adjust your pasteurization procedure based on load in incoming product?
    a. ___ Yes
    b. _9_ No
11. Do you test for –
    a. _10_ Salmonella post-pasteurization?
    b. _10_ Standard plate count post-pasteurization?
    c. _8_ Other (please specify coliform, e-coli, yeast, mold, listeria and staph)

12. Do you use SE vaccines or buy eggs from companies who vaccinate flocks?

d. _2_ Yes

e. _5 _ No

f. _3_ Don't know

13. If you answered "yes" to question 12, do you or your supplier use –

a. __ Live vaccine?

b._1_Killed vaccine?

c._1_ Combination of live and killed vaccines?

14. If you answered "yes" to question 12, approximately what percentage of your eggs come from vaccinated flocks? ________________________________

15. Are you aware of any instance of documented human illness from consuming pasteurized egg products –

No-8___ From your facility?

No-8___ From the facility of another egg processor?

12. If you answered "yes" to either part of question 16, please describe the situation.

____

PLEASE RETURN THIS SURVEY NOT LATER THAN FRIDAY, NOVEMBER 19 TO DR. GLENN FRONING AT gfroning@neb.rr.com

Comments from Survey

Question 1:

d. Log reductions for our products range from minimum of 7 to more than 12

Question 2:

c. USDA approved pasteurization parameters to achieve a 7 log reduction of Salmonella populations.

Company policy and type of products

Process Efficiency

Question 3:

d. Log reduction targets for processes are set depending on the product and intending use. Specific pathogen reductions and/or control of heat resistant spoilage microbes are used in determining the pasteurization conditions. Key data used are D-values for pathogens and flow conditions in holding tubes.

Question 5:

Whites lowest and whole egg highest.

Found mostly with EW and Salt yolk. We find closer to 5 log kills with these products, mostly because of temp parameters and stringency of Salt.

Question 7:

c. In a 1998 study, we determined that 34% of our incoming egg tankers were positive for Salmonella. The level of Salmonella in positive samples varied from .003 cfu/gram to >1.1 cfu/gram.

Routine plating of incoming egg product.

We test raw egg products off the breaking rooms and in raw product vats, as well as incoming tankers for APC and Y&M daily. (Two identical answers)

Questions 8c:

70%

Question 9c:

Limited testing for specific microbes.

Periodically

(Total coliform, E.coli) We do not wait for results prior to pasteurization

Question 11c:

Listeria, Staph, coliforms, yeast/mold, specific spoilage microbes as required by customers.

Coliform, E.coli, yeast, mold and staph

Coliform, Yeast/mold

Total coliform, E. coli

Y&M, Staph, E. Coli, total coliform, Listeria; others on request

E. coli, coliforms as well

Total coliform, E. Coli, Listeria (Refrigerated Liquid Egg Products

Question 14:

Approximately what percentage of your eggs come from vaccinated flocks?

30%

85-90%